PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference RLL-304WO	**FOR FURTHER ACTION** See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/IB 03/04162	International filing date *(day/month/year)* 24.09.2003	Priority date *(day/month/year)* 24.09.2002
International Patent Classification (IPC) or both national classification and IPC A61K9/16		
Applicant RANBAXY LABORATORIES LIMITED		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
23.04.2004	17.01.2005
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Vermeulen, S Telephone No. +49 89 2399-7520

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/IB 03/04162

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-13 as originally filed

Claims, Numbers

1-55 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 44-55

because:

☒ the said international application, or the said claims Nos. 44-55 relate to the following subject matter which does not require an international preliminary examination (specify):

see separate sheet

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the said claims Nos.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the Standard.

☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	23-43
	No:	Claims	1-22,44-55
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-55
Industrial applicability (IA)	Yes:	Claims	1-43
	No:	Claims	

2. Citations and explanations

see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

Claims 44-55 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(I) PCT).

Re Item V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Reference is made to the following document/s/:

   D1: FR-A-2 819 720 (FOURNIER SA LAB) 26 July 2002
   D2: WO 02/11699 A (IMPAX LAB INC) 14 February 2002
   D3: FR-A-2 795 961 (ETHYPHARM LAB PROD ETHIQUES) 12 January 2001

2. The subject-matter of independent claims 1 and 44 is not considered novel (Art. 33(2) PCT) in view of prior art disclosures which can be taken from D1 and D2.

   D1 (cf. Example 1) and D2 (cf. page 9, lines 1-24 ; Table 1, Table 7) disclose the association of micronized fenofibrate with an insoluble inert carrier, i.e. microcrystalline cellulose (D1, D2) and pregelatinized starch (D1). In both cases the obtained product is a granulate comprising the inert carrier and the micronized fenofibrate together with a binder (e.g. PVP or HPMC) and a surfactant (e.g. sodium lauryl sulfate). The production process comprises mixing the inert carrier with the micronized fenofibrate in powder form and granulating the mixed powders with a solution comprising the binder and surfactant. Hence, the process of D1 and D2 differs from the process disclosed in the present application, because in the latter the powdered inert carrier is granulated with a solution comprising a binder, surfactant and the micronized fenofibrate. The obtained granulates, however, are very likely to be identical. At least, it is not clear how the final products in D1 and D2 should be distinguished from those of the present application. Accordingly, the granulates of D1 and D2 are considered to fall within the definition of the present claim 1. As a consequence, the method of claim 44 is also not considered novel in view of D1 (cf. page 13, lines 4-6) and D2 (cf. page 3, lines 23-26).

3. The subject-matter of independent claim 23 is not considered to involve an inventive step (Art. 33(3) PCT) in view of prior art disclosures which can be taken from D1 and D2.

D1 (e.g. page 10, example 1) and D2 (e.g. page 9, Table 1 ; page 13, Table 7) both disclose fenofibrate formulations with enhanced bioavailability, wherein the same surfactants, same hydrophilic polymers and same fillers are used in very similar proportions to those defined in the present claims. The percentages defined in the above mentioned claims do furthermore not appear to solve any problem posed and merely fall within amounts which are common in the art.

4. The process according to independent claim 30 is not considered to involve an inventive step in view of the teaching in D1, D2 and D3.

The claimed process differs from that of D1 (cf. Example 1) and D2 (cf. page 9, lines 11-22) only in that the micronized fenofibrate is dispersed in the granulating liquid, whereas in D1 and D2 the micronized fenofibrate is provided in powder form mixed with the inert carrier and subsequently wet granulated. No technical effect can be seen on the final product provided by this difference. The present application discloses improved solubility and bioavailability of the fenofibrate (cf. description page 7, lines 14-16). This is however also disclosed in D1 (cf. page 5, lines 28-31) and D2 (cf. page 2, lines 13-22 ; page 3, lines 19-22). Accordingly, the process of the present application is considered as an alternative to D1 and D2. However, granulation processes, wherein micronized fenofibrate is dispersed in the granulating liquid, are generally known and disclosed e.g. in D3 (cf. page 4, lines 19-27). Suspending the fenofibrate in the granulating liquid is accordingly considered as an obvious modification from which the skilled person would select, when looking for an alternative process.

5. In view of the state of the art disclosed in D1, D2 and D3 also the dependent claims 2-22, 24-29, 31-43 and 45-55 do not appear to contain any additional features which, in combination with the features of any claim to which they refer, would render the claimed subject-matter novel and/or inventive (Art.33(2)-(3) PCT). None of the specific embodiments appears to provide a solution to any problem, which solution involves an inventive step, as compared to the cited prior art

6. The subject-matter of claims 1-43 is considered to be industrially applicable and accordingly meets the requirements of Art.33(4) PCT.